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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/727,543

12/05/2003

Todd A. Hall

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7346

7590

06/08/2007

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EXAMINER

PHILOGENE, PEDRO

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

06/08/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/727,543

Applicant(s)

HALL ET AL.

Examiner

Pedro Philogene

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 109-189 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 109-189 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 109-189 are rejected under 35 U.S.C. 102(e) as being anticipated by Makower (5,830,222).

With respect to claims 109 and 148, Makower discloses a method of bypassing a blockage in a coronary vessel, comprising creating a channel extending at least partially by advancing a needle (5) through the heart wall from a location substantially proximal to the blockage to a location substantially distal to the blockage in the coronary vessel; as best seen in FIG. 12; advancing a guide wire (28) through the channel (36) or needle (5), advancing an implant (41) over the guide wire into the channel; as best seen in FIG.4; and positioning the implant such that blood flows through the implant and into the coronary vessel distal to the blockage; as set forth in column 3, lines 46-67; column 4, lines 40-65, column 8, lines 24-67, column 9, lines 37-67.

With respect to claims 110-147, 149-189, Makower discloses all the limitations; as set forth in column 3, lines 46-67; column 4, lines 40-65, column 8, lines 24-67,

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column 9, lines 37-67, column 9, lines 14-67, column 10, lines 1-67, and as best seen in FIGS. 1-29.

***Response to Amendment***

Applicant's arguments, see Remarks, filed 3/23/07, with respect to claims 109-189 have been fully considered and are persuasive. The rejection of claims 109-189 over DP and Goldstein has been withdrawn.

Applicant's arguments filed 3/23/07, with respect to Makover, have been fully considered but they are not persuasive. Applicant stated "Clearly, an "interstitial space" is not a heart wall"; applicant also stated "the specification says "through the surrounding tissue" not "through the myocardium" or "through the heart wall". To interpret the phrase "through surrounding tissue" to mean "through the heart wall" is an interpretation of Makeover Fig. 19B based on hindsight provided by applicants' disclosure". First applicant's attention is directed to column 1, lines 23-27, where Makover discloses creating a channel into a heart wall. Second, applicant's attention is again directed to column 3, line 1-5, and line 24-28, where Makover discloses the use of a device for creating an opening to by pass a lesion within the coronary artery in the heart. Applicant stated that "through surrounding tissue" not "through the myocardium"; however, applicant's attention is directed to column 9, lines 40-67, FIGS. 20, 20A, 20B, where Mekover discloses the use of tunnels or openings through the myocardium. As to advancing a needle through a heart wall, first the guide wire of Makover could be considered as a needle, second Maekover discloses, column 8, lines 50-61, that many devices may be inserted for effecting a medical intervention. Devices include needles.

Therefore, Makeover, discloses the use of a device for creating a channel extending at least partially in a heart wall and also advancing a needle through a heart wall and into a portion of the coronary vessel.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

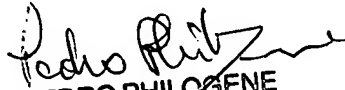
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (571) 272-4716. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272 - 4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Pedro Philogene  
June 3, 2007

  
PEDRO PHILOGENE  
PRIMARY EXAMINER